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First Named Inventor

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Assistant Commissioner for Patents BOX PATENT APPLICATION Washington, D.C. 20231

Sir:

Enclosed for filing is a complete patent application, entitled "METHOD AND APPARATUS FOR DISPLAYING PHYSIOLOGICAL PATIENT DATA" invented by:

11-14-00

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and including the following documents:

Specification including Claims - 14 pages
Abstract of the Disclosure
Drawings - 5 sheets
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Declaration, Power of Attorney
Check No. 109044 for \$1,572.00 for filing fee
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Petition to Accept Color Drawings Under 37 CFR § 1.84(a)(2)
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TOTAL CLAIMS	59 - 20	= 39	x \$18.00	=	\$702.0
INDEPENDENT CLAIMS	5 - 3	= 2	× \$80.00	=	\$160.0
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Respectfully submitted,

Thomas A. Miller Reg. No. 36,871

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Date: 11/13/2000

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# METHOD AND APPARATUS FOR DISPLAYING PHYSIOLOGICAL PATIENT DATA

The invention relates to a method and apparatus for displaying physiological patient data from a cyclic physiological waveform, and particularly, to a method and apparatus for displaying physiological patient data from a cyclic physiological waveform in a colorized three-dimensional representation.

Medical patient monitors are typically employed by physicians and other health care providers to monitor the physiological data of patients in operating rooms, intensive care units and emergency rooms, and for conducting long-term trend monitoring such as Holter monitoring or stress testing.

An array of sensors (also commonly called transducers) are typically connected to the patient to acquire the various physiological data. These data are then displayed on the screen of a monitor either in graphical or numerical form. These data may also be recorded or displayed on analog or digital strip chart recorders, spreadsheets and plotting programs.

In prior patient monitoring systems, and particularly in Holter and stress testing systems, it was found to be advantageous to take a series of successive periods of physiological patient data and cascade the periods in a quasi-three-dimensional display format to render visually obvious the abnormalities attendant to certain physiological conditions. However, this kind of data presentation can become cluttered if too many waveform samples are displayed at any one time. Moreover, some users of the equipment find such a display presentation visually unappealing, notwithstanding the clinical importance of the display technique.

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### SUMMARY OF THE INVENTION

Accordingly, the invention provides a method of displaying physiological and/or pathological patient data from a cyclic physiological or pathological waveform. Hereinafter, the terms "physiological data" or "physiological patient data" shall be broadly defined as including pathological data, or any other type of patient information that is capable of being displayed using the invention. The method includes acquiring the physiological patient data, storing the physiological patient data in a waveform array, and displaying the physiological patient data on a display with a color component that is capable of plotting a three dimensional representation of the data. Although it is not possible to display a three dimensional graph on a two dimensional display, the display represents a three dimensional graph by stacking two dimensional waveforms offset of each other to denote perspective or depth. This method of displaying allows the operator to view a two dimensional image that represents a three dimensional image. Hereinafter, the "X coordinate" shall denote the respective position of each data point with respect to time, the "Y coordinate" shall denote the amplitude of each data point, and the "Z coordinate" shall denote the respective temporal alignment, or offset position of each successive waveform. In one form of the invention, the step of displaying the physiological patient data includes parsing the waveform array into a series of successive waveforms such that each successive waveform is plotted in a temporal alignment to allow easy detection of long term trends in physiological data, parsing each successive waveform into a series of successive data points such that each data point is plotted at a representative X coordinate, Y coordinate, and Z coordinate, and assigning a color (which may be a shade of gray in the case of a black and white monitor or a variation in intensity in the case of a monochrome monitor) according to the amplitude of the data point. The waveform array may be physiological data that represents individual physiological cycles such as heart beats, or the waveform array may be data that has been aggregated in some fashion such as averaging or filtering, or reduction to a median complex.

The invention also provides an apparatus for acquiring and displaying physiological patient data. The apparatus includes a sensor or a transducer for

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acquiring physiological patient data from a patient, a processor for receiving the physiological patient data, storing the physiological data in a waveform array, and for generating a waveform display on a display. The processor parses the waveform array into a series of successive waveforms, and assigns each successive waveform a respective Z coordinate. The processor also divides each waveform into a series of successive data points and assigns each data point a respective X coordinate. Next, the processor assigns a color (which may be a shade of gray in the case of a black and white monitor, or a variation in intensity in the case of a monochrome monitor) according to the Y coordinate of the data point and plots the data point on the display monitor so that the pixel at the respective coordinate is energized using that color.

It is an advantage of the invention to provide a method and apparatus of displaying amplitude differences of physiological patient data using a gray scale or color display three-dimensional representation.

Other features and advantages of the invention are set forth in the following drawings, detailed description and claims.

# BRIEF DESCRIPTION OF THE DRAWINGS

The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Fig. 1 is a block diagram illustrating a patient monitoring system according to the invention.

Fig. 2 is a flow chart illustrating the method of the invention.

Figs. 3(a) and 3(b) are two color illustrations showing three dimensional representations of physiological patient data from a cyclic physiological waveform according to the invention.

Figs. 4-7 are examples of rotated or animation views of the three dimensional representations according to the invention.

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Fig. 8 is a schematic representation of the method of coloring the display as shown in Figs. 3(a) and 3(b).

# DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Before one embodiment of the invention is explained in full detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including" and "comprising" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

Fig. 1 illustrates the patient monitoring system 10 of the invention. The patient monitoring system 10 acquires and displays physiological patient data from a cyclic physiological waveform. While the monitoring system 10 can be used in connection with any kind of clinical environment, in the preferred embodiment, the monitoring system 10 is for conducting long-term trend monitoring such as in Holter monitoring or stress testing. Monitoring system 10 is coupled to the patient 14 by an array of sensors or transducers which may include, for example, electrodes 18 mounted on the patient's chest for determining electrocardiogram and heart rate, an oximetry sensor 22 mounted on the patient's finger for measuring hemoglobin oxygen saturation, a catheter 26 for measuring hemoglobin oxygen saturation in the vena cava in the central venus pressure, an arterial canula 30 for measuring arterial systolic and diastolic pressures, flow meter 34 and a pressure sensor 38 in the endotrachial tube 42 for measuring trachial gas flow, and airway pressure, respectively, and sensors 46 in the patient's mask 50 for measuring the volume percentage of oxygen and CO2 in the patient's mouth. Hereinafter, the terms "sensor" and "transducer" will be used synonymously, and each term will be defined as including the subject matter of the other term.

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The signals derived from the sensors are converted from analog form to digital form by the analog to digital converter 54 and are then provided to a processor 58 that prepares the data for display on display monitor 62. The monitor is a conventional computer-style display monitor having a generally rectangular cathode ray tube or CRT (not shown). The CRT includes a plurality of pixels. As is known in the art, each pixel is capable of being energized electronically so that the pixel emits light visible to the user of the monitoring system.

In the preferred form of the invention, the display monitor 12 is capable of displaying full color pixels, i.e., the display monitor is an RGB color monitor capable of displaying 256 colors or more. In other embodiments however, a black and white display capable of showing black, white and a plurality of gray shades (preferably no less than 64) in between is acceptable. The term "color" as used in this application is used to indicate either true color or shades of gray as described above unless the context indicates otherwise. Also, while any physiological patient data may be displayed in the format of the preferred embodiment, the invention will be discussed in the context of displaying long-term electrocardiogram ("ECG") data. As is commonly known in the art, the ECG data is subjected to (input 2) a software program that averages or "incrementally" averages the data to produce a series of median waveform complexes. These median waveform complexes are often separated and visually stacked on a display to provide an easily viewable representation of a significant amount of ECG data.

Figure 2 illustrates a flowchart of a method embodying the invention. The waveforms (or in the case of the preferred embodiment, the median waveform complexes) are stored in a waveform array, are processed by the software routine stored in the processor 58, and are displayed on the display monitor 62 in a quasi-three-dimensional color display. The display includes x, y, and z axes where the x-axis coordinate represents the data point of a given median waveform complex, the y-axis coordinate represents the amplitude of the data point, and the z-axis coordinate represents the median waveform complex.

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The processor sets the current waveform count to the first waveform in the waveform array, i.e., the processor initializes the z coordinate 100 (Z = 0). The processor then initializes the x coordinate counter (X = 0) and reads the amplitude of the first data sample 200. The processor then sets a variable (START POINT) to be the present data point (which at the beginning of the process is X = 0; Y = presentamplitude value; and Z = 0) 300. The software then increments the x coordinate value by one in order to read the next data point and then reads the amplitude of that data point 400. Next the software sets the variable (END POINT) to be the incremented xyz coordinate 500. The processor then draws two triangles between the data points and colors the triangles based on the amplitude color-code 600. While any color code can be used, including gray scale and variations in intensity, the color code of the preferred embodiment is illustrated in Figs. 3(a) and 3(b) in the lower left hand corner of these figures. As shown in Figs. 3(a) and 3(b), the color-code establishes a different color for amplitude values ranging between negative 0.5 millivolts and positive 0.5 millivolts. The software program draws the triangles by establishing a quadrilateral around the START POINT and END POINT variables, 610 and 620, respectively, of the present median beat 625, and the START POINT and END POINT variables 630 and 640, respectively, of the previous median beat 645 with the same X-coordinate value as the START POINT and END POINT variables 610 and 620 (see Fig. 8). Next, the software dissects the quadrilateral by establishing a line between the START POINT variable 610 and the END POINT variable 640. The color is then set for the display based on the amplitude value of the START POINT variable 610 using the amplitude color-code. The software then changes the START POINT variable to END POINT variable 700, and determines whether the data point is the last data point of the present median beat or median complex 800. If not, the software program returns to set the START POINT variable 300 and repeats process steps 300 through 800 until the last data point of the median beat is analyzed. At that point, the software program increments the z coordinate to read the next median beat 900. The software program then determines alternatively whether the median beat is the last median beat of the stress test or whether the data point being analyzed is the last data point of the data set 1000. If not, the software program repeats the process starting at act 200. If so, the software process ends.

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In the preferred form of the invention, the color scheme of the monitoring system 10 is fully configurable. That is, the user can select any color to represent a given amplitude. Alternatively, the monitoring system 10 is programmed to provide the user with a set of manufacturer defined color schemes. In the preferred form of the invention, there is graphical and numerical information generated on the display to indicate the corresponding voltage level of displacement for each color used.

As shown in Fig. 3, the successive waveforms are plotted in a stacked colorized representation to provide a perspective or representative three dimensional view of the physiological patient data over an extended period of time. This presentation highlights subtle trends that may exist in the data, but are difficult to observe with ordinary display presentations. In a preferred form of the invention, the representative three dimensional view of the data can be rotated by the processor so that it can be viewed on the display by the user from different perspectives. The use of color to enhance this display allows easy detection by the clinician of significant aspects of the data, for example, the yellow and orange portions of the data displayed in Fig. 3 indicate a significant S-T depression in the ECG data.

Figs. 4 - 7 illustrate how the representative three dimensional view of the data can be rotated by the processor so that it can be viewed on the display by the user from different perspectives. Essentially, the processor rotates the representative three dimensional image by rotating the X, Y, and Z axes. As the image rotates, the operator is able to more easily characterize different segments of the median waveforms. For example, when using median ECG waveforms, the operator may be able to more easily characterize the difference in amplitudes of the median waveforms using a view similar to Fig. 7. The operator may rotate the image a full 360 degrees in order to view each side of the image.

Various other features and advantages of the invention are set forth in the following claims.

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#### **CLAIMS**

What is claimed is:

1. A method of displaying physiological patient data from a cyclic physiological waveform, the patient data including a plurality of data points, each data point representing the amplitude of the physiological patient data, the method comprising the acts of:

acquiring the physiological patient data; and displaying the physiological patient data in a three dimensional representation.

- 2. A method as set forth in claim 1, wherein the physiological data is electrocardiogram data.
- 3. A method as set forth in claim 1, wherein the physiological data is blood pressure data.
- 4. A method as set forth in claim 1, wherein the physiological data is cardiac output data.
- 5. A method as set forth in claim 1, wherein the physiological data is pulse oximetry data.
- 6. A method as set forth in claim 1, and further comprising the acts of storing the physiological patient data in a memory array.
- 7. A method as set forth in claim 6, wherein the memory array is a waveform array.
- 20 8. A method as set forth in claim 1, and further comprising the acts of parsing the physiological patient data into a series of waveforms.
  - 9. A method as set forth in claim 8, wherein the series of waveforms are median waveforms.

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- 10. A method as set forth in claim 8, wherein the act of displaying includes the act of plotting the parsed waveforms in a temporal alignment to allow detection of long term trends in physiological data.
- 11. A method as set forth in claim 1, wherein the act of displaying further includes the act of assigning a representative X coordinate, Y coordinate, and Z coordinate, to each data point and plotting each data point on the display to produce a three dimensional representation.
- 12. A method as set forth in claim 1, further including the act of parsing the data points into a series of median waveforms and wherein the act of displaying further includes the act of plotting the waveforms in a temporal alignment.
- 13. A method as set forth in claim 1, wherein the act of displaying further includes the act of color-coding the amplitude values of the data points in the relevant range.
- 14. A method as set forth in claim 13, wherein the relevant range is +0.5mV to 0.5mV.
- 15. A method of displaying physiological patient data from a cyclic physiological waveform, the method comprising:

acquiring the physiological patient data;

storing the physiological patient data in a memory array; and

displaying the physiological patient data in a three dimensional representation, the act of displaying including parsing the physiological patient data into a series of waveforms such that each successive waveform is plotted in a temporal alignment to allow detection of long term trends in physiological data, the act of parsing each waveform into a series of successive data points such that each data point has a coordinate that is plotted on the display to produce a three dimensional representation, each successive data point having a discrete amplitude, and assigning a color according to the amplitude of the data point if the amplitude is within the relevant range.

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- 16. A method as set forth in claim 15, wherein said physiological patient data is electrocardiogram data.
- 17. A method as set forth in claim 15, wherein the physiological data is blood pressure data.
- 18. A method as set forth in claim 15, wherein the physiological data is cardiac output data.
- 19. A method as set forth in claim 15, wherein the physiological data is pulse oximetry data.
- 20. A method as set forth in claim 15, wherein the memory array is a waveform array.
- 21. A method as set forth in claim 15, wherein the series of waveforms are median waveforms.
- 22. A method as set forth in claim 15, wherein the relevant range is +0.5 mV to -0.5 mV.
- 23. An apparatus for displaying physiological patient data from a cyclic physiological waveform, the data including a plurality of data points having an amplitude representing the value of the physiological parameter, the apparatus comprising:

a display; and

- a processor for producing a three dimensional representation of the physiological patient data.
- 24. An apparatus as set forth in claim 23, and further comprising a patient monitor device as the source of physiological patient data.

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- 25. An apparatus as set forth in claim 24, wherein the patient monitor device includes a transducer for acquiring the physiological patient data from a patient.
- 26. An apparatus as set forth in claim 24, wherein the patient monitoring device is a Holter monitor.
  - 27. An apparatus as set forth in claim 24, wherein the patient monitoring device is a stress-testing monitor.
  - 28. An apparatus as set forth in claim 23, and further comprising a memory device connected to the processor.
  - 29. An apparatus as set forth in claim 28, wherein the physiological patient data is stored as a memory array.
  - 30. An apparatus as set forth in claim 29, wherein the memory array is a waveform array.
- 31. An apparatus as set forth in claim 23, wherein the display is a black and white display capable of displaying/generating shades of gray in between black and white.
  - 32. An apparatus as set forth in claim 23, wherein the display is a red-blue-green color display.
- 33. An apparatus as set forth in claim 23, wherein the display has a plurality of pixels for displaying the respective coordinates.
  - 34. An apparatus as set forth in claim 23, wherein the processor further comprises software for animation and walk through of three-dimensional representations.
  - 35. An apparatus as set forth in claim 23, wherein the processor further comprises software for receive physiological data.

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- 36. An apparatus as set forth in claim 23, wherein the processor further comprises software to parse the physiological data.
- 37. An apparatus as set forth in claim 36, where in the physiological data is parsed into a series of waveforms.
- 38. An apparatus as set forth in claim 37, wherein the series of waveforms are median waveforms.
- 39. An apparatus as set forth in claim 23, wherein the processor further comprises software to generate a waveform display on the display.
- 40. An apparatus as set forth in claim 39, wherein the waveform display places the data points at respective pixels on the display.
- 41. A software program for generating a display of physiological data from a cyclic physiological waveform, the software program comprising:
  - (a) a program module for acquiring the physiological patient data;
  - (b) a program module for storing the physiological patient data in a memory array;
  - (c) a program module for displaying a three dimensional representation;
  - (d) a program module for setting the current waveform to the first waveform in the waveform array;
  - (e) a program module for providing a Z coordinate counter and initializing the Z coordinate counter to zero;
  - (f) a program module for providing a X coordinate counter and initializing the X coordinate counter to zero;
  - (g) a program module for providing a Y coordinate counter and initializing the Y coordinate counter to zero;
  - (h) a program module for providing a determining the pixel color based on the Y coordinate of the data point;
  - (i) a program module for plotting the current data point of the current waveform at the current coordinate in the color determined in (h);

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- (j) a program module for incrementing the X coordinate counter and repeating (h) and (i) until all data points in the current waveform are plotted; and
- (k) a program module for incrementing the Z coordinate counter and repeating (h)-(j) until all waveforms in the waveform array are plotted.
- 42. An apparatus for displaying physiological patient data from a cyclic physiological waveform, the data including a plurality of data points having an amplitude representing the value of the physiological parameter, said apparatus comprising:

a display;

- a means for producing a three dimensional representation of the physiological patient data.
- 43. An apparatus as set forth in claim 42, and further comprising a patient monitor device as a source of physiological patient data.
- 44. An apparatus as set forth in claim 43, wherein the patient monitor device includes a transducer for acquiring the physiological patient data from a patient.
- 45. An apparatus as set forth in claim 43, wherein the patient monitor device is a Holter monitor.
- 46. An apparatus as set forth in claim 43, wherein the patient monitor device is a stress-testing monitor.
  - 47. An apparatus as set forth in claim 42, wherein the means for producing a three dimensional representation includes storing the physiological data.
- 48. An apparatus as set forth in claim 47, wherein the physiological patient data is stored in a memory array.
  - 49. An apparatus as set forth in claim 48, wherein the memory array is a waveform array.

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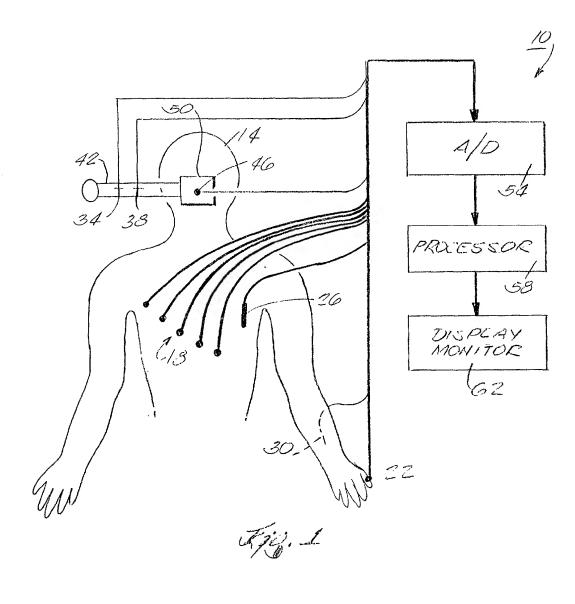
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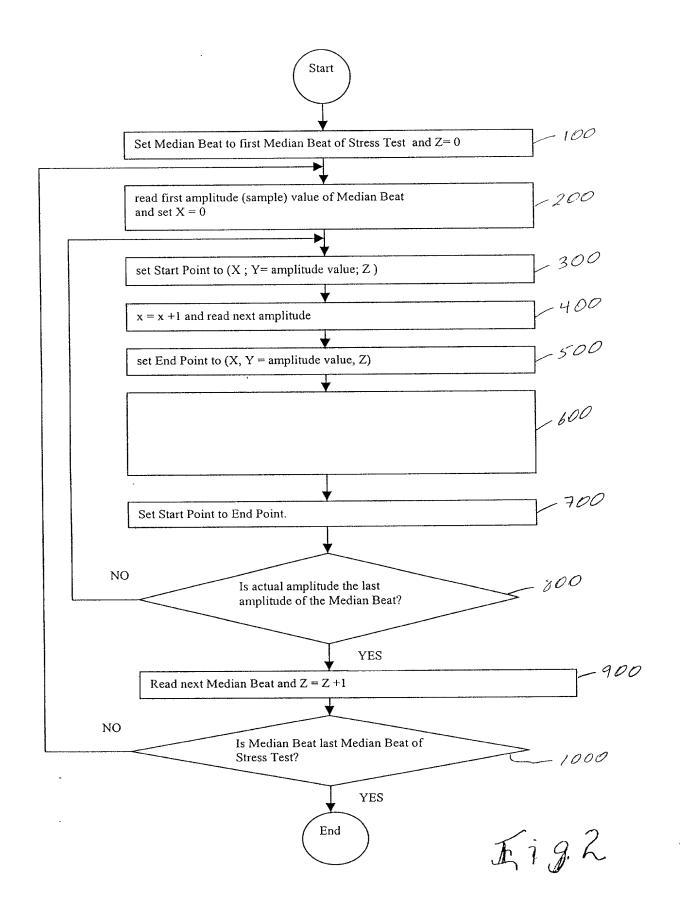
- 50. An apparatus as set forth in claim 42, wherein the display is a black and white display capable of displaying/generating shades of gray in between black and white.
- 51. An apparatus as set forth in claim 42 wherein the display is a red-blue-green color display.
  - 52. An apparatus as set forth in claim 42, wherein the display has a plurality of pixels for displaying the respective coordinates.
  - 53. An apparatus as set forth in claim 42, wherein the means for producing a three dimensional representation includes animating the three dimensional representation for analysis of the three dimensional representation.
  - 54. An apparatus as set forth in claim 42, wherein the means for producing a three dimensional representation includes receiving physiological data.
  - 55. An apparatus as set forth in claim 42, wherein the means for producing a three dimensional representation includes parsing the physiological data.
  - 56. An apparatus as set forth in claim 55, where in the physiological data is parsed into a series of waveforms.
    - 57. An apparatus as set forth in claim 56, wherein the series of waveforms are median waveforms.
  - 58. An apparatus as set forth in claim 42, wherein the means for producing a three dimensional representation includes generating a waveform display on the display.
    - 59. An apparatus as set forth in claim 58, wherein the waveform display places the data points at respective pixels on the display.

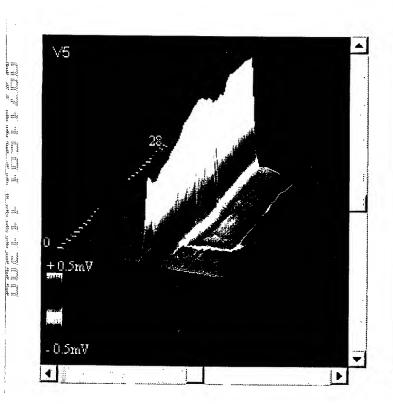
## **ABSTRACT**

A method and apparatus for acquiring and displaying physiological patient data from a cyclic physiological waveform in a three dimensional representation wherein the amplitude of the data is represented in color and displayed.

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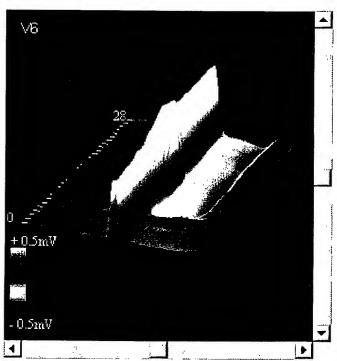


Fig. 3



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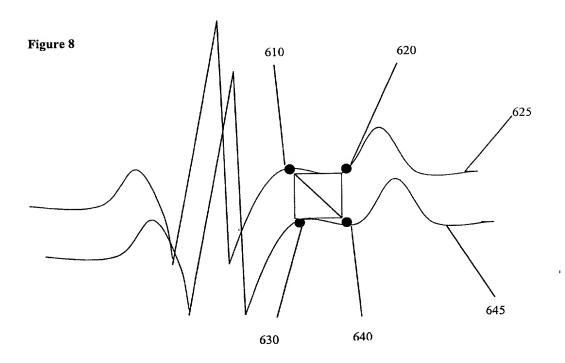
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### Declaration and Power of Attorney For Patent Application

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled "METHOD AND APPARATUS FOR DISPLAYING PHYSIOLOGICAL PATIENT DATA" (Attorney Docket No. 39199/9505), the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims referred to above.

I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

And I hereby appoint Thomas A. Miller (Reg. No. 36,871), Christopher B. Austin (Reg. No. 41,592), David L. De Bruin (Reg. No. 35,489), Gerald L. Fellows (Reg. No. 36,133), Randall W. Fieldhack (Reg. No. 43,611), Joseph A. Gemignani (Reg. No. 19,482), Gregory J. Hartwig (Reg. No. P-46,761), Daniel S. Jones (Reg. No. 42,697), Richard L. Kaiser (Reg. No. 46,158), Timothy M. Kelley (Reg. No. 34,201), Casimir F. Laska (Reg. No. 30,862), Edward R. Lawson, Jr. (Reg. No. 41,931), Richard H. Marschall (Reg. No. 39,290), Kevin P. Moran (Reg. No. 37,193), Andrew R. Peret (Reg. No. 41,246), David R. Price (Reg. No. 31,557), Thomas S. Reynolds II (Reg. No. 45,262), David B. Smith (Reg. No. 27,595), Derek C. Stettner (Reg. No. 37,945), Billie Jean Strandt (Reg. No. 36,940), Sheldon L. Wolfe (Reg. No. 43,996) of Michael Best & Friedrich LLP, 100 East Wisconsin Avenue, Milwaukee, Wisconsin 53202; Paul F. Donovan (Reg. No. 39,962), Jill A. Fahrlander (Reg. No. 42,518), Grady J. Frenchick (Reg. No. 29,018), Karen B. King (Reg. No. 41,898), Linda Blair Meier (Reg. No. 39,769), Teresa J. Welch (Reg. No. 33,049) of Michael Best & Friedrich LLP, Firstar Plaza, One South Pinckney Street, Madison, Wisconsin 53703; Robert S. Beiser (Reg. No. 28,687), Witold A. Ziarno (Reg. No. 39,888) of Michael Best & Friedrich (Illinois), 77 West Wacker Drive, Suite 4300, Chicago, Illinois 60601-1635; Christian G. Cabou (Reg. No. 35,467), Phyllis Y. Price (Reg. No. 34,234), Michael A. Della Penna (Reg. No. 45,697) of GE Medical Systems, 3000 North Grandview Boulevard, Waukesha, Wisconsin 53188; Ronald E. Myrick (Reg. No. 26,315), Henry J. Polcinski (Reg. No. 26,621), Jay L. Chaskin (Reg. No. 24,030) of General Electric Company, 3135 Easton Turnpike, Fairfield, Connecticut 06431, and each or any of them, my attorneys or agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

# ADDRESS ALL COMMUNICATIONS IN OR PERTAINING TO THIS APPLICATION TO:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

	te the validity of the application or any patent issued	
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Inventor's signature Date: Residence: Citizenship: Post Office Address:	10/19/2000 Denzlingen, Germany Germany Berliner-Strasse 20 Woepplinsberger-Strasse 18 79211 Denzlingen, Germany 79312 Emmendingen, German	ny
Full name of second joint	inventor: Thomas Friedrich Eberle	
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Full name of third joint inventor: Rolf Band

Inventor's signature 73 4

Date: 09/22/2000

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